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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/820,816 | 04/09/2004 | Ara Hovanessian | 02356.0091 | 9491 |

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| EXAMINER | |
|---|---|
| BOESEN, AGNIESZKA | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1648 | |

DATE MAILED: 05/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/820,816 | HOVANESSIAN ET AL. | |
| | Examiner | Art Unit | |
| | Agnieszka Boesen | 1648 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *09 April 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-32* is/are pending in the application.

4a) Of the above claim(s) *10,11,23,24,27,29 and 31* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-9, 12-22, 25-27, 28, 30, and 32* are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

The Office notes that claims 10, 11, 23, 24, 27, 29, and 31 are drawn to claims that recite, "Use of". "Use" claims are non-statutory under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example Ex parte Dunki , 153 USPQ 678 (Bd. App. 1967) and Clinical Products, Ltd v. Brenner,255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966). See MPEP 2173.05(q).

Therefore, claims 10, 11, 23, 24, 27, 29, and 31 have been withdrawn from consideration as being drawn to a non-statutory subject matter.

Claims 1-9, 12-22, 25, 26, 28, 30, and 32 are pending and are subjected to the following restriction.

### *Election/Restrictions*

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-9, 13-16, 26, 28, and 32 drawn to a pharmaceutical composition comprising at least one peptide, classified in class 530, subclass 300.

If group I is elected Applicant is further required to elect **one** amino acid sequence: SEQ ID NO: 1, SEQ ID NO: 2, SEQ ID NO: 3, SEQ ID NO: 4, SEQ ID NO: 5, SEQ ID NO: 6, SEQ ID NO: 7, SEQ ID NO: 8, or SEQ ID NO: 9.

II. Claim 17, drawn to a nucleic acid encoding the peptides of any one of sequence SEQ ID NO: 1 to SEQ ID NO: 9 and SEQ ID NO: 11 to SEQ ID NO: 18, classified in class 536, subclass 23.1.

If group II is elected Applicant is further required to elect **one** amino acid sequence: SEQ ID NO: 1, SEQ ID NO: 2, SEQ ID NO: 3, SEQ ID NO: 4, SEQ ID NO: 5, SEQ ID NO: 6, SEQ ID NO: 7, SEQ ID NO: 8, SEQ ID NO: 9, SEQ ID NO: 11, SEQ ID NO: 12, SEQ ID NO: 13, SEQ ID NO: 14, SEQ ID NO: 15, SEQ ID NO: 16, SEQ ID NO: 17, or SEQ ID NO: 18.

III. Claim 18-20 and 22 drawn to monoclonal, polyclonal and oligoclonal antibodies, classified in class 530, subclass 387.1.

IV. Claims 21, drawn to a method for detecting the presence of HIV in a biological sample, classified in class 435, subclass 5.

V. Claim 25, drawn to a method of measuring the presence of neutralizing antibodies in a biological sample, classified in class 435, subclass 7.1.

VI. Claim 30, drawn to a method of selecting or isolating anti-HIV molecules, classified in class 435, subclass 5.

The inventions are distinct, each from the other because of the following reasons:

The composition comprising polypeptides of group I and isolated nucleic acid of group II are patentably distinct inventions for the following reasons. Peptides, which are composed of amino acids, andnucleic acids, which are composed of purine and pyrimidine units, are structurally distinct molecules; any relationship between a polynucleotide and polypeptide is dependent upon the information provided by the nucleic acid sequence open reading frame as it corresponds to the primary amino acid sequence of the encoded polypeptide. In the present claims, a nucleic acid of group II does not necessarily encode a peptide of group I. In addition, while a peptide of group I can made by methods using some, but not all, of the nucleic acids that fall within the scope of group II, it can also be recovered from a natural source using by biochemical means. For instance, the polypeptide can be isolated using affinity chromatography. For these reasons, the inventions of group I and II are patentably distinct.

Furthermore, searching the inventions of groups I and II together would impose a serious search burden. In the instant case, the search of the polypeptides and the nucleic acids are not coextensive. The inventions of groups I and II have a separate status in the art as shown by their different classifications. Prior to the concomitant isolation and expression of the sequence of interest there may be journal articles devoted solely to polypeptides, which would not have described the polynucleotide. Similarly, there may have been "classical" genetics papers, which had no knowledge of the polypeptide but spoke to the gene. Therefore searching the nucleic acids and peptides, is not coextensive. The scope of nucleic acids as claimed extend beyond the polynucleotide that encodes the claimed polypeptides as explained above; furthermore, a search

of the nucleic acid molecules of group II would require an oligonucleotide search, which is not likely to result in relevant art with respect to the peptides of group I. As such, it would be burdensome to search the inventions of groups I and II together. Furthermore, searching all sequences of nucleic acids together and all sequences of peptides would require using commercial databases and there is search burden also in the non-patent literature. Thus groups I and II are properly restricted based on being independent or distinct and having a burdensome search requirement.

The peptide of group I and the antibody of group III are patentably distinct for the following reasons: While the inventions of both group I and group III are polypeptides, in this instance the polypeptide of group I is a single chain molecule that functions as an enzyme, whereas the peptide of group III encompasses antibodies including IgG which comprises 2 heavy and 2 light chains containing constant and variable regions, and including framework regions which act as a scaffold for the 6 complementarity determining regions (CDRs) that function to bind an epitope. Thus the peptide of group I and the antibody of group III are structurally distinct molecules; any relationship between a peptide of group I and an antibody of group III is dependent upon the correlation between the scope of the polypeptides that the antibody binds and the scope of the antibodies that would be generated upon immunization with the polypeptide.

Furthermore, searching the inventions of group I and group III would impose a serious search burden. The inventions have a separate status in the art as shown by their different classifications. A peptide and an antibody which production is induced as result of the immunization with the peptide require different searches. An amino acid sequence search of the

full-length protein is necessary for a determination of novelty and unobviousness of the protein. However, such a search is not required to identify the antibodies of group III. In addition, the technical literature searches for the peptide of group I and the antibody of group III are not coextensive, e.g., antibodies may be characterized in the technical literature prior to discovery of or sequence of their binding target.

The polynucleotide of group II and the antibody of group III are patentably distinct for the following reasons. The antibody of group III includes, for example, IgG molecules which comprise 2 heavy and 2 light chains containing constant and variable regions, and including framework regions which act as a scaffold for the 6 complementarity determining regions (CDRs). Polypeptides, such as the antibody of group III which are composed of amino acids, and polynucleotides, which are composed of nucleic acids, are structurally distinct molecules; any relationship between a polynucleotide and polypeptide is dependent upon the information provided by the nucleic acid sequence open reading frame as it corresponds to the primary amino acid sequence of the encoded polypeptide. In the present claims, a nucleic acid of group II will not encode an antibody of group III, and the antibody of group III cannot be encoded by a polynucleotide of group II. Therefore the antibody and polynucleotide are patentably distinct.

The antibody and polynucleotide inventions have a separate status in the art as shown by their different classifications. Furthermore, searching the inventions of group II and group III would impose a serious search burden since a search of the nucleic acid of group II is would not be used to determine the patentability of an antibody of group III, and vice-versa.

Inventions I and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the peptide of group I can be used in the method of immunization against HIV as opposed to being used as a method of measuring the neutralizing antibody in a biological sample. The literature search regarding the peptide of group I will not necessarily reveal the literature regarding the method of measuring the neutralizing antibody in a biological sample. Because the inventions III and IV have acquired a separate status in the art the restriction for examination purposes is proper.

Inventions (I, II) and (IV, VI) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions, the peptides of group I and the nucleic acids of group II are not disclosed as being used in the methods of HIV detection of group IV or the method of selecting or isolating anti-HIV molecules of group VI. The different inventions have different modes of operation such as a gene therapy mode of operation of group II, which is different from the HIV detection of group IV, or the method of selecting or isolating anti-HIV molecules of group VI. It is an undue burden for the examiner to search more than one invention. Therefore restriction for examination purposes is proper.

Inventions (II, III) and (V, VI) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions, the nucleic acids of group II and the antibodies of group III are not disclosed as being used in the method of measuring the presence of antibody of group V or in the method of selecting or isolating anti-HIV molecules of group VI. The different inventions have different modes of operation such as a gene therapy mode of operation of group II, which is different from measuring the presence of antibody of the neutralizing in a biological sample of group V or selecting or isolating anti-HIV molecules of group VI. It is an undue burden for the examiner to search more than one invention. Therefore restriction for examination purposes is proper.

Inventions III and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibody of group III can be used in the method of passive immunization against HIV as opposed to being used as a method of detecting the HIV. The literature search regarding the antibody of group III will not necessarily reveal the literature regarding detection of HIV. Because the inventions III and IV have acquired a separate status in the art the restriction for examination purposes is proper.

Inventions IV, V, and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). The instant specification does not disclose that these methods would be used together. The method of detecting the HIV in a biological sample, the method of measuring the presence of the antibody, and the method of selecting and isolating the HIV molecule are unrelated as they comprise distinct steps and utilize different products which demonstrates that each method has a different mode of operation. Each invention performs this function using a structurally and functionally divergent material. Moreover, the methodology and materials necessary for detection of HIV in a biological sample differ significantly from the method of selecting and isolating the HIV molecule. Therefore, each method is divergent in materials and steps. For these reasons the inventions IV, V, and VI are patentably distinct. Furthermore, the distinct steps and products require separate and distinct searches. The inventions of groups IV, V, and VI have a separate status in the art as shown by their different classifications. As such, it would be burdensome to search all inventions together.

Because the inventions are distinct for the reasons given above and the literature and sequence search required for one group is not co-extensive with any other group, and therefore presents a serious burden of search, restriction for examination as indicated is proper. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

*Notice of Possible Rejoinder*

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the

product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

### *Conclusion*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Agnieszka Boesen, Ph.D. whose telephone number is 571-272-8035. The examiner can normally be reached on M – F (9:00AM - 6:00PM).
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

AB

Agnieszka Boesen, Ph.D.

April 27, 2006

James C. Housel

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